Re-thinking pharmaceutical production in Africa

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Title: Re-thinking pharmaceutical production in Africa; insights from the analysis of the local manufacturing dynamics in Mozambique and Zimbabwe

Authors: Giuliano Russo[1,2,*], Geoffrey Banda[3]

* corresponding author. grusso@ihmt.unl.pt.

Affiliations:

[1]International Health and Biostatistics Unit, Instituto de Higiene e Medicina Tropical, Nova University of Lisbon. Rua da Junqueira 100, Lisbon (Portugal)

[2]Institute of Development Studies, Library Road, University of Sussex, Brighton, East Sussex BN1 9RE (United Kingdom)

[3]The Open University. Walton Hall, Milton Keynes, Buckinghamshire MK7 6AA, (United Kingdom)

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Pharmaceutical manufacturing dynamics in Mozambique and Zimbabwe

Abstract

Until recently consensus existed in certain circles that the African industry was not suitable for cost-effective production of quality, safe drugs. Yet public and private pharmaceutical enterprises have cropped up on the continent, with some venturing into production of sophisticated and complex drugs, such as antiretrovirals (ARVs). In our study we analyse and contrast the dynamics of local pharmaceutical manufacturing in Mozambique and Zimbabwe with the objective of understanding why pharmaceutical production in Africa is picking up momentum, and the influence of global funding for ARVs in this process. Our analysis identifies two routes of development for local pharmaceutical manufacturing: a favourable economic outlook and support from the international community created the necessary conditions for the development of the nascent pharmaceutical industry in Mozambique, while in Zimbabwe the presence of an established local industry was instrumental in bringing in favourable, if not always coherent, government regulation. In both countries, the introduction of AIDS treatment created windows of opportunity for local production of pharmaceuticals by increasing public sector demand, providing fresh funds, and providing a justification for government regulation favouring local production. Despite the long-standing and well-known problems that created persistent shortcomings in human resources, as well as the economic and industrial environments, we conclude that pre-existing developmental roots, international funds and supportive state industrial policies are encouraging more manufacturers to enter the business of local pharmaceutical production in Africa. However, the opportunities brought in by fresh AIDS funds will need to be sensibly managed at both the local and global levels, as the world's interest on the disease may not last in the long term.

Key-words: Medicines in Africa; pharmaceutical manufacturing; pharmaceutical markets; Mozambique; Zimbabwe.

1 Introduction

In this paper we explore the dynamics of pharmaceutical manufacturing in Mozambique and Zimbabwe and the impact of the introduction of antiretroviral (ARV) treatment on the industry, with the objective of shedding light on an important but still understudied topic and contributing to the wider debate on local production of drugs in low-income settings. We selected the two countries as they both have attributes that make them likely and unlikely candidates for local production, and their distinct political economic contexts led to different industrial responses to the same trigger – the AIDS pandemic. Zimbabwe has a long history of industrial development, but it has been undergoing economic and political crisis for a decade. Mozambique is one of the poorest and least developed countries in the world, but it is a darling of international donors, and its pharmaceutical sector in particular has enjoyed strong support from Brazil.

By analysing the evolution of the two industries, their progress and setbacks, as well as the role played by national governments and international community in the process, we aim to offer insights into the possible advantages of local production of drugs, the hurdles encountered in setting it up, and the opportunities – as well as challenges – presented by the global push for AIDS treatment. Through our case studies we identify one route of development for local pharmaceutical manufacturing passing through favourable economic conditions and support from the international community, and another taking advantage of an established pre-existing local industry and favourable government regulation. In both cases, the introduction of AIDS treatment created windows of opportunity for local production of pharmaceuticals by increasing public sector demand, providing fresh funds, and providing a justification

for government regulation favouring local production. Like the other papers in the special issue, the present work aims at closely examining widely held assumptions regarding pharmaceuticals and access to medicines in developing countries, in this case by examining the debate around local pharmaceutical production in Africa.

The next section reviews the debates regarding the local production of pharmaceuticals in low- and middle-income countries. The following third and fourth sections present the two case studies of Mozambique and Zimbabwe, focusing on the key changes to these countries' policies and regulations toward pharmaceutical development, changes introduced by ARV production, and hurdles encountered by local manufacturers. In section five we contrast the enabling factors and stumbling blocks identified across the two settings, and extract lessons for wider debates on local production and the effects of the global response to AIDS on the landscape of the pharmaceutical sector in Africa. In the sixth section we conclude with a summary of our findings and the contributions that our analysis makes to debates on local pharmaceutical production in Africa.

2 Local pharmaceutical production in Africa

Despite accounting for 25% of the world's burden of disease (Institute for Health Metrics and Evaluation and Human Development Network the World Bank 2013) access to medicines in African countries remains limited on account of the unavailability of many drugs at affordable prices (Cameron et al. 2009). As Africa imports the vast majority of the pharmaceutical products consumed (UNCTAD 2013), many take the view that fostering local production could be an effective way to improve access to medicines by shortening the supply chain and cutting down import costs, and at the same time helping the development of the continent's industrial complex (Chaudhuri, Mackintosh, and Mujinja 2010; UNIDO-AUC 2012). The literature

suggests a number of arguments supporting the logic of local production of pharmaceuticals, such as: (a) the need for a stable and reliable drug supply to attend healthcare goals; (b) the ability to provide for specific local needs; (c) flexibility and ability to adapt to a changing epidemiological profile, and; (d) its ability to identify local product markets and willingness to distribute outside major urban centres (Shadlen and Fonseca 2013; Mujinja et al. 2014). Experiences from Asia and Latin America also show that local production of pharmaceuticals can be efficient (Kuanpoth 2007), strategic for implementing national health policies (Flynn 2008), and in some cases, may end up having global health and industrial repercussions (Waning, Diedrichsen, and Moon 2010).

However, given the dramatic price reductions brought by Asian generic drugs, a commonly held view is that, rather than investing in the local industry, focussing on world-wide procurement of inexpensive drugs would be a more efficient use of African governments' drug funds (WHO 2011). Others maintain that African countries often lack the critical mass of industrial services and human capital required to produce quality drugs at competitive prices (Kaplan and Laing 2005), and that local manufacturing could do little in the way of reducing the upward pressure on drug prices from international patents (Rovira 2006). As also shown by other papers in this special issue, to a large extent the AIDS epidemic has come to amplify the terms of the debate on pharmaceuticals and the developing world, by compounding its share of the burden of disease, demand of high-value products, need of affordable treatment, and opportunities to exploit Trade-related Intellectual Property Rights (TRIP) flexibilities (Benatar 2004).

Recent efforts to map out the pharmaceutical manufacturing industry in Africa by the African Union - Global UNIDO Project (UNIDO-AUC 2012) and the GIZ project to survey manufacturing capabilities in Eastern Africa (GIZ 2012) highlighted how,

despite the shortcomings of weak industrial and governance environments, local production of pharmaceuticals in Africa has developed progressively since the 1930s, with numerous pharmaceutical factories having started operations in Africa, and 38 countries in the continent presently estimated to have operating pharmaceutical manufacturing entities. Although incomplete, fragmented and focussing mostly on English-speaking economies, the existing information on Africa's pharmaceutical production capabilities paints a picture of consistent development of the industry, with the first local operations by international companies started between the 1930s and 1960s in South Africa, Nigeria, Zimbabwe and Morocco, followed by a second wave of locally-owned companies in Uganda, Nigeria, Kenya, Tanzania and Botswana in the 1970s and 1980s (Figure 1).

<Insert Figure 1 here>

While the early genesis of local manufacture especially in Nigeria and Zimbabwe was linked to multinational firms establishing subsidiaries in colonies, during the later part of the 1960s onwards, local entrepreneurs with experience in the multinational pharmaceutical companies started setting up their own production facilities. Currently, the majority of the existing pharmaceutical manufacturers in Africa are reported to be small, locally-owned private companies that primarily serve local markets, although larger state-owned enterprises are also being established[1]. International importers and

[1] Such as Saidal in Algeria and Saphad in Tunisia.

distributors are also reported to keep setting up their own plants on the continent or entering joint ventures with local manufacturers[2] (UNIDO 2010).

The proliferation of pharmaceutical enterprises over multiple countries paints a picture of a dynamic manufacturing terrain that has shown pharmaceutical companies rising in different geographies, with little comprehensive information on the nature and extent of the industry being collected, consolidated and disseminated. A patchwork of mostly descriptive studies currently exists on pharmaceutical manufacturing in Africa as well as on other low- and middle-income settings; an analysis and comparison of such diverse experiences is what appears to be missing, identifying commonalities and possible paths to development. Our paper sets out to fill this gap by analysing and contrasting the dynamics of pharmaceutical manufacturing in Mozambique and Zimbabwe, with the objective of contributing to the current understanding of why pharmaceutical production in Africa is picking up momentum, and the influence of global funding for ARVs in this process.

3 Pharmaceutical manufacturing in Mozambique

Mozambique is a low-income country (LIC) ranking 185th out of 187 in the United Nations Human Development Index. Having achieved independence from Portugal in 1975, Mozambique experienced 16 years of civil war that profoundly affected the country and its health care system. Following the 1992 Rome peace accords, these days Mozambique is rapidly developing, thanks to substantial Overseas Developing

[2] For example CIPLA and Quality Pharmaceuticals in Uganda.

Assistance funds first, and then by the recent discovery of natural resources. However, the recent economic growth has exacerbated socio-economic differences, fuelling discontent on the government's less-than-ideal record on governance (Fairbairn 2013). With an average health spending of just USD35 per capita, the Mozambican health care system finds itself under continued pressure because of population high mortality and morbidity rates, not least because of the HIV/AIDS infection (Table 1).

<Insert table 1 here>

Mozambique's post independence pharmaceutical policy was praised as one of Africa's most progressive, as its cash-strapped Government, heavily dependent on foreign aid and drug imports, adopted a strict essential drugs list approach, nationalised procurement and distribution, and focussed on generic drugs to extract the best possible value from its drug budget (Barker 1983). In the last decade Mozambique has become one of the world's largest recipients of health aid funds (Van de Maele, Evans, and Tan-Torres 2013), with international drug funds managed first through an externally-managed Drugs Common Fund (Pavignani and Durão 1999), and subsequently through an MoH-managed Sector Wide Approach common fund agreement (PROSAUDE). With the global push for AIDS fight and the introduction of Antiretroviral Treatment (ART) in 2003, the country started benefitting from a considerable injection of AIDS funds, with Antiretroviral drugs procured in the international market by organisations like the Global Fund, the World Bank and USAID. Such drugs are imported in kind to the country to be distributed by the Ministry of Health through its system and to foreign AIDS Non-Governmental Organisations, despite the scarcity of pharmaceutical skills and the absence of an updated National Pharmaceutical Policy. The soon to be approved national plan to scale up ART aims

at taking advantage of donors' profligacy for this area and provide treatment to 80% of the infected.

Local production of pharmaceuticals is nascent in Mozambique, as only 1 producer exists, having started production in 2013 with support from the Brazilian government. The market is currently dominated by the public sector that imports drugs through the MoH Central Drugs and Medical Supplies Agency (CMAM) and by a highly concentrated group of private importers/wholesalers selling to a retailing network of 264 private pharmacies, 40 publicly owned retailers, and occasionally to CMAM.

The pharmaceutical market in Mozambique was estimated to be worth approximately USD140 million in 2012 in terms of the value of drugs imported (COWI 2012), which represented a drug expenditure of USD5.55 per capita. Approximately USD 122 million (85%) of the total market value was represented by public sector imports, the vast majority of which was funded by external funds and donations, some of them managed by the local Ministry of Health (MISAU) through the sector budget support fund - PROSAUDE (CMAM 2011). Between 2004 and 2012 public drugs expenditures went from USD 78 million to 122 million, the increase being driven by in-kind AIDS drugs donations, that went from the original USD4 million to the current 49 in eight years (COWI 2012).

<Insert table 2 here>

AIDS drugs expenditures were the single largest budget item in 2012, representing 40% of all the public sector drugs, and were imported into the country exclusively as in-kind donations managed directly by the responsible international organizations. State Budget funds contributed to 18% of the overall public sector drug expenditures,

while North-America-based organizations (USAID and the Clinton Health Access Initiative – CHAI) contributed to import 68% of all the AIDS drugs in the country.

<Insert table 3 here>

Little consolidated data exists about the private pharmaceutical market, with some estimates putting it at approximately USD 20 million, calculated on the basis of the drugs value declared on the import documents submitted to the pharmaceutical department in 2012 (COWI 2012). Currently, although 54 private importers are officially registered in Mozambique, the private sector is highly concentrated, with the 4 largest firms covering above 50% of the drugs imported (Medis, Maputo Healthcare, Generics and Specialties, and Welworth). Of the 2,572 pharmaceutical products currently registered for importation by private operators in Mozambique, 55% are of Indian origin, followed by 12% of drugs from Portugal and 5% from Brazil and Germany (COWI 2012).

3.1 Regulation of the sector

Regulation of the sector is based on the 1996 Pharmaceutical Sector Strategic Plan (MISAU 1996). The MoH's Pharmaceutical Department (recently re-named Hospital Pharmacies Directorate) is in charge of the regulation of the sector, supported by the Inspection Directorate and the National Laboratory for Drugs Quality Control (LNCQM) and advised on specific pharmacological issues by the Therapeutic Technical Commission, an unelected body composed of notable physicians from the Maputo Central Hospital. All drugs entering the country are required to seek registration with the Pharmaceutical Department; since little capacity exist within LNCQM for laboratory analysis, as in many other African countries, the Drug Registration System is the main

tool to guarantee the quality of the imported drugs, and individual importers are responsible and held accountable for the quality of the drugs they import. No bioequivalence standards exist for generics; inspectorate reports and anecdotal evidence suggest that, although safety is not an issue, the quantity of active substance in drugs available in the Mozambican market can be diverse, especially across non-branded generics from less well-known Indian manufacturers (Russo and McPake 2010).

CMAM is responsible for planning, procuring and distributing drugs for the public sector. CMAM typically uses limited open tender procedures to procure drugs locally as well as internationally; by law, bids by national providers are given preference as long as their price does not exceed 15% of the cheapest competing international bid (COWI 2012). Local suppliers are often resorted to in case of emergencies and (frequent) drugs stock-outs, in order to shorten the regular drug acquisition cycle, estimated to last in excess of 265 days, depending on the type of funds used. In a move to promote national production, primary chemical products – such as pharmaceutical Active Pharmaceutical Ingredients (APIs) – have been exempted from import duties (de Oliveira 2013).

In theory, the private sector has been regulated by quality, profession and price legislation since the 1990s, but in practice, even such less-than-detailed regulation has not been substantiated by real enforcement. Privately imported medicines are licensed and registered by the Pharmaceutical Department, and are subject to chemical analysis by the National Medicine Quality Control Laboratory. MISAU regulation establishes pharmacy venues and warehousing standards, and pharmacies are subject to internal inspections. Prices are regulated through a cost-plus system fixing cost and profit mark-ups for each stage of medicine distribution (Government of Mozambique 1990, 1998, 2003). A recent study showed that private operators often

disregard such mark-ups and profit margins, given MoH's limited enforcement capacity (Russo and McPake 2010).

In the last decade the sector has tried unsuccessfully to reform its drug registration and pricing systems (Russo and McPake 2010), with the objective of increasing the quality of the drugs imported, and expanding the range of drugs available in the country. Despite a recent botched attempt to reform profit margins and mark-ups (GoM 2010), strongly resisted by both private importers and local distributors, at the time of writing, the private sector pricing regulation in force is still that dating back to 1990.

3.2 The SMM's experience

Mozambique's Pharmaceuticals Limited (*Sociedade Moçambicana de Medicamentos*, SMM) is a public enterprise set up on the outskirts of Mozambique's capital city to locally manufacture pharmaceuticals with the financial and technical support of the Brazilian cooperation. The Brazil-Mozambique collaboration started in 2003 after an agreement between former presidents Lula and Chissano, and was developed during the last decade as a 'South-South' cooperation project, seeing the involvement of multiple Brazilian and Mozambican players and going through a number of political, international relations and industrial processes (Russo, Cabral, and Ferrinho 2013). The original agreement had the stated objectives to: (a) expand the population's access to ART in the country; (b) build local production of generic pharmaceuticals; (c) reduce dependence on international pharmaceutical imports, and; (d) contribute to building local pharmaceutical capacity in Mozambique (de Oliveira 2013). The Government of Brazil (GoB) committed to providing funds for staff training and capacity building, equipment, technical assistance, raw materials, design of the factory and management; the Government of Mozambique took responsibility to purchase the infrastructure for the factory, to undertake rehabilitation works, and for the factory's

recurrent expenditures, including local staff's salaries, and to purchase drugs from SMM.

The Oswaldo Cruz Foundation (Fiocruz) - Brazil's leading public health institution – conducted the factory's feasibility study in the three following years, and, after negotiating the financial support of VALE – a Brazilian mining company with operations in Mozambique – infrastructure works were finalised in 2012. Farmanguinhos – Fiocruz's pharmaceutical arm – donated equipment, pharmaceutical production technology files and technical assistance, and production of Nevirapine, Lamivudine, Captopril and Hydrochlorothiazide started in 2013 (Russo et al. 2014).

So far, SMM is the only pharmaceutical factory in Mozambique, as premises and equipment of the previous existing factory was purchased to make space for SMM's operations. The Government of Mozambique's State Shareholding Management Institute (IGEPE) owns the factory project, while the chair of its administrative board is appointed by MISAU, as is the executive director of the factory.

SMM is located in the Greater Maputo Area on a 20,000-m^2 allotment close to the capital's commercial port and to the South African border. The factory currently operates two production lines, one devoted to hospital drippings and other large volume liquid pharmaceutical compounds, and the other to solid compressed pharmaceutical compounds. According to its business plan (SMM and Farmanguinhos 2013) the factory will produce 17 different pharmaceutical items including 6 Antiretroviral products (ARVs) with an annual production capacity of 226 million units of ARV and 145 million units of other medicines (see the full list in Annex I). SMM will engage in both secondary and tertiary pharmaceutical production (that is, large-scale processing of finished pharmaceutical compounds and packaging and labelling imported drugs, respectively), without directly producing APIs (which is defined as primary production).

The factory's staff requirements amounts to 88 full-time workers (24 for direct production, 4 for quality control-related services, and 18 for management and administration); at the time of writing only 70 personnel had completed their training and had been recruited, and the 2 most senior technical managers were Brazilian cooperation staff. In terms of equipment, 18 high-tech pieces have been procured internationally and donated by the Brazilian cooperation.

According to the factory's business plan, SMM should be able to sell its products at prices comparable to those from the international market thanks to savings in the initial investment in infrastructure and equipment – donated by the Brazilian cooperation – in national transport charges and taxes – particularly favorable to business in Mozambique since the original tax rate on chemical products was scrapped. In comparison to the typical cost structure for ARVs (Pinheiro et al. 2006), SMM's production costs will be largely driven by Active Pharmaceutical Ingredients' (APIs) imports, and less by taxes, profit margins, research and development and local production mark-ups (SMM and Farmanguinhos 2013). Despite the expected savings in local production costs, dependency on the volatile global market for APIs is recognized to be a liability for SMM.

Factory's sales forecasts predict that, given the installed capacity and under the assumption of sustained low local costs and continued Brazilian support, in the next three years SMM should be able to put on the market approximately six million USD worth of drugs, which should turn the enterprise sustainable by the fifth year of production (SMM and Farmanguinhos 2013). As things stand, the national public and private markets represent the factory's customer base, but the wider Southern Africa pharmaceutical market should be targeted once all the necessary international quality certifications are obtained (COWI 2012). However, despite the optimism of these predictions, as the largest proportion of the factory's output is expected to be sold to

the NHS, MISAU's commitment to absorb SMM's production will be crucial for the financial success of the enterprise.

3.3 Identified bottlenecks for pharmaceutical manufacturing in Mozambique

The analysis of the SMM experience shows that pharmaceutical manufacturing is kicking-off in Mozambique thanks to the Brazilian and Mozambican government support, but the reluctance of private investors to get into this business area signals the presence of numerous issues hampering the development of a local pharmaceutical industry.

Human resources were identified as the single most important bottleneck for SMM development, as of the 88 staff considered essential to run the factory's operations, 75 had to be sent for training abroad, some of the pharmacists currently employed are at risk of being poached by competing businesses in wholesaling and retailing, and senior executive positions are still covered by expatriate staff. As pharmacy degrees have been offered by local university for relatively little time, no pharmacological technology specialization exists in the country as yet, and a cap of 5% in the proportion of a company's foreign staff has been imposed by the Government, a medium to long term investment in training local staff abroad appears as the only way for the industry to recruit the specialists cadres needed to carry out technical tasks. Although personnel with middle-management skills seem to be already supplied by the Mozambican labor market, experienced executives with a track record of senior management in comparable industries are acutely lacking in Mozambique, given the country's relatively recent history of industrial development.

Mozambique's industrial environment was also recognized as another factor hampering the development of the Brazilian sponsored pharmaceutical factory. Consistent with the literature on pharmaceutical manufacturing in Africa (Kaplan and

Laing 2005), Mozambique seems to be lacking a 'critical mass' of suppliers, products and services needed for the development of a competitive business. In SMM's specific case, all the primary products for the transformation of compounds are imported from Brazil, and all the basic maintenance and technical services are contracted to South African firms, adding on in terms of costs and delays to the production lines. For the SMM case, the option to resort to lower-cost Indian and Chinese equipment had to be set aside, given the limited equipment maintenance services provided by such suppliers in Africa. SMM's APIs come subsidized by Brazilian suppliers, which only transform the original chemical products imported mostly from India, and in part from China – the so-called secondary production. Some pharmaceutical importers in Mozambique have resorted to 'downstream vertical-integration' of their business to the retailing level, in order to benefit from a leaner production chain and from the regulated profit margins associated with each distribution stage, while at the same time minimizing the risk associated with having to rely on an uncertain industrial environment (Russo and McPake 2010).

Despite the country's favorable regulation of chemical imports' tax and duties, governance was reported to be a key hurdle for the long-term development of pharmaceutical manufacturing in Mozambique. The Government's ineffective quality control of pharmaceutical manufacturing processes and final products may allow *de facto* the employment of cheaper substandard machinery in pharmaceutical production and the presence on the market of substandard generic products. Despite cutting costs and bureaucracy, the Government's failure to implement quality controls is pushing local suppliers towards the lower end of the pharmaceutical market, where costs and prices need to be low to face off international competition. Lack of effective quality regulation is believed to benefit those importers of non-branded generics for whom an ability to cut costs and offer wildly discounted generics represents the core of their

market strategy in Mozambique. Together with the high risk of the local business environment, with bank loans' typically high interest rates, the loose protection of property rights and the poor governance typical of the country, contributes to turning pharmaceutical manufacturing unpalatable for most entrepreneurs in Mozambique.

Finally, the local funding environment still represents a critical limitation for pharmaceutical production in Mozambique. Given people's limited ability to pay and the lesser size of the private sector, selling to the public sector is the only way for local producers to go to scale and access a market worth in excess of USD140 million in Mozambique. However, as public purchase of drugs is overwhelmingly funded by international donors – either through sector budget support or in kind donations, as in the case of ARVs – large international tenders tend to be the norm for the acquisitions of public sector drugs. As a result, local producers are left with limited chances to tap into a demand for pharmaceuticals that is typically met by free donations, or by purchases from the world's most efficient producers.

4 Zimbabwe's pharmaceutical sector

Zimbabwe is a land-locked southern African country bordered by South Africa, Botswana, Mozambique and Zambia. It has a population of 13.7 million and among the world's worst health indicators (Table 1). The country's public health delivery system is structured to serve the populace at local, district, provincial and national health institutions through a referral system. As at 2012, Zimbabwe had an HIV/AIDS prevalence of almost 15% (1.4 million people infected with HIV) down from 32% recorded at the height of the HIV/AIDS epidemic.

Having attained independence and democracy in 1980, Zimbabwe went through a decade of a state-managed economy to accelerate development, unlock its economic potential and address equity issues. The decade commencing from the 2000s saw a

deterioration of the country's economic conditions, fuelled by hyperinflation and international economic sanctions (Brett 2005). Only after 2008 did Zimbabwe's GDP go back to positive growth rates, following a political power-sharing agreement and the easing of international sanctions (World Bank 2013).

Since independence the government took a primary care as well as industrial development approach in the organization of its health care services. The 1987 National Drug Policy (NDP) contained provision to promote the use of generic drugs in both public and private sectors and elaborated an Essential Drug List for Zimbabwe (Turshen 2001). The NDP also established a Regional Medicines Quality Control Laboratory (Froese 1991); a fresh NDP was elaborated in 1999 promoting local manufacturing of essential drugs, as well as local research and development and technical collaboration within the region, and to the present days Zimbabwe is one of the few African countries with an effective drug quality control system (UNIDO 2011).

Because of the increase in AIDS prevalence, in 2002 the government invoked Trade Related Intellectual Property Rights flexibility and issued compulsory licenses to local pharmaceutical operators to manufacture and import generic AIDS drugs. A national AIDS Levy was introduced in 2006 to fund the purchase of ARV in local currency. By 2003 international donations by the Global Fund and the Presidential Aids Relief Initiative started importing internationally procured ARVs with WHO or Food and Drug Administration quality certifications (UNIDO 2011).

Zimbabwe's 2013 allocated annual health expenditure was US$381 million, representing 10% of total national expenditure. As much of the initially allocated budget does not get spent on drugs, and a considerable share of international drug donations fail to appear in the official budget books, many health professionals and policy makers consider the system as substantially funded through bilateral and multilateral donors.

Official World Bank statistics refer to a USD85 health expenditure per capita for 2012 (World Bank 2013).

Business Monitor International estimates that pharmaceuticals expenditure for 2013 in Zimbabwe was US$ 223 million up from US$ 203 million in 2012 (BMI, 2009); generic drugs constituted 68.5% of the total drug market in Zimbabwe and over the counter segment came in at 22.5%. Healthcare spending was forecasted to increase from US$220 million in 2009 to US$650 million by 2014. Government in 2012 allocated for medical care services (inclusive of drugs supply) US$63.3 million. Availability of essential drugs was estimated to range between 29–58%, and other essential drugs' availability ranged from 22–36% compared to a national target of 75–80% (National Budget, 2012).

Zimbabwe has historically enjoyed some self-sufficiency in drug supply (Turshen, 2001), and at that time larger scale pharmaceutical production was targeting the larger Central African Federation and exports into the rest of Africa. The industry claims to be able to supply 122 products out of the 260 essential drugs for Zimbabwe; 46% of the country's essential drugs (UNIDO, 2011b and NECF, 2011). When new product development initiatives underway are factored in, local drug provision can rise to 75% of essential drugs and contribute 5% to GDP (NECF, 2011). However, currently the local industry is not supplying as much drugs to the public health systems as in the past. Table 4 below shows how dependent the country has been on pharmaceutical imports from 2006 to 2011. Pharmaceutical imports increased from US$ 39.2 million in 2006 to US 89.4 million in 2011 reflecting low industrial capacity utilisation caused by hyperinflation, shortage of foreign currency and infrastructural failure.

<Insert table 4 here>

Procurement of drugs in general for the public health system is managed by Natpharm using funds from the health budget and Natpharm's own resources, however approval by the State procurement board is required for tenders. There are private sector distribution agents/wholesalers who sell mainly to private hospitals and pharmacies (ZPCP, 2011). However procurement of ARVs, especially for Global Fund programmes, is done through international tenders through the UN pooled procurement by UNICEF, as UNDP is the principal recipient of the funds in Zimbabwe. The National Aids Council (NAC) manages the procurement of drugs using funds raised through the AIDS levy. Other multi-lateral and bilateral donors use their in-house procurement vehicles and procure drugs mostly from outside the country.

Funding for ART (anti-retroviral treatment) programmes in Zimbabwe in some respect received extra attention from government and the donor community alike. The government of Zimbabwe enacted the National Aids Council (NAC) Act in 1999, which gave rise to the National Aids Trust Foundation entrusted with administering the AIDS levy. The primary local source of funding for the antiretroviral treatment programme in Zimbabwe is the AIDS levy. The AIDS levy was initially set up as a drought levy by the government to raise funds to mitigate the effects of drought in the country. When HIV AIDS became a challenge this drought levy was converted into an AIDS levy through government legislation by the Ministry of Finance. The government collects 3% tax from all formally employed people and the funds are allocated to NAC through the National Aids Trust Fund (NATF). The requirement set by government is that 50% of the resources must be used to procure drugs for HIV/AIDS related illnesses.

After pegging the local Zimbabwean dollar to a basket of international currencies, the Aids levy has contributed significantly to the ART programme supporting 24 per cent of patients on ART in 2010. The bulk of funding however came from Global Fund

(35%), USA government (18%) and the Extended Support Programme that was led by DFID of UK (22%). Collections for the NAC for 2010 were US$ 39.9 million; made up of US$ 20.5 from AIDS levy and US$ 18.7 million from donors. Of the US$ 20.5 million from the AIDS levy, 50% is required to be used for drug procurement.

Collection of the AIDS levy in the era after dollarization of the Zimbabwean economy rose to US$ 32.5 million from a base of US$ 5.7 million in 2009 (Table 5), and based on the 2006 Government policy, 50% of the AIDS levy was allocated to ARV drug procurement. NAC procured ARV medicines valued at US$ 18.5 million in 2012 up from the previous year's US$ 5.2 million (NAC, 2012).

<Insert table 5 here>

However, the bulk of HIV/AIDS funding has historically come from the bilateral and multilateral donor community and total expenditures were US$ 35.4 million (2007), US$ 25 million (2008) and US$ 37.8 million (2009) (UNGASS report, 2009). Fifty per cent of the AIDS levy goes towards treatment and ARV drug procurement progressively increased from US$ 0.89 in 2009 to US$ 18.6 million in 2012 (Table 5). Expenditure on ARVs of US$ 18.6 million implies a viable local market for the local pharmaceutical industry to support; if they can produce competitively ARVs needed for recommended treatment regimens in Zimbabwe.

4.1 The pharmaceutical industry in Zimbabwe

The pharmaceutical industry in Zimbabwe dates back to 1953 driven by the country's early industrial development. In 1990 Zimbabwe was, after South Africa, touted as the African country with potential to become the next newly industrialising country because of its established and vibrant manufacturing sector. However the pharmaceutical

industry currently concentrates on secondary and tertiary production only, and there are currently no subsidiaries of large multinational pharmaceutical companies operating manufacturing plants in Zimbabwe (UNIDO, 2007, 2011b). There are currently nine pharmaceutical manufacturing companies registered with the Medicines Control Authority of Zimbabwe (MCAZ), and of these, five, are the major generic manufacturers accounting for 90% of the formulation businesses (UNIDO, 2011b). According to Seiter's (2005) classification, Zimbabwean pharmaceutical companies fall into the category of generics companies with predominantly national operations and small-to medium scale local manufacturers limited to formulation development, production and packaging activities. These local generics manufacturing companies operate in a competition intensive, low margin, commodity-type business, where profitability and long-term viability depend on economies of scale, assured demand and large markets (Berger et al., 2009; Kaplan and Laing, 2005).

Zimbabwean pharmaceutical companies by the early 2000s (prior to the onset of the economic downturn) were exporting pharmaceutical drugs to South Africa, Zambia, Namibia, Malawi, Tanzania, Burundi, Rwanda, Botswana, Democratic Republic of Congo, Mauritius, Kenya, Uganda and Mozambique. The companies had registered products in Kenya, Tanzania, Malawi, Zambia, Mozambique, Lesotho, Swaziland, Namibia, Uganda and South Africa (UNIDO 2007).

The medical regulatory authority that oversees the pharmaceutical manufacturing industry is the Medical Control Authority of Zimbabwe (MCAZ). MCAZ is responsible for pharmaceutical surveillance, licensing, enforcement, laboratory services, evaluation and registration activities for the sector.

From a human capabilities perspective, the pharmaceutical industry is supported with engineering, chemistry, microbiology and pharmacy graduates from local universities and polytechnics. Zimbabwe used to have a robust technical training policy through

the polytechnics that was funded by the Zimbabwe Manpower Development Fund (Zimdef); students were supported through university by government loans and grants. The school of pharmacy critical to supplying pharmaceutical research and development as well as production skills was established in 1974 as a department within the College of Medicine at the University of Zimbabwe and has played a major role in strengthening human capabilities in the local industry in spite of brain drain for the last fifteen years.

4.2 ARV manufacturing in Zimbabwe

Zimbabwe's pharmaceutical industry has long been capable of manufacturing drugs locally, and the country was one of the first African countries to use the compulsory licensing route to effect local production of ARVs for public use to address the HIV/AIDS pandemic (Osewe, Nkrumah, and Sackey 2008). In 2002 the government of Zimbabwe declared an HIV/AIDS state of emergency, and invoked section 35 of the Zimbabwean patents act, which authorises a third party to manufacture and sell products (Sacco 2004). Thus the government in 2002 issued the General Notice 240 of 2002, which allowed local production, use and import of any patented drug including any antiretroviral used in the treatment of persons suffering from HIV/AIDS or any HIV/AIDS related conditions[3]. The initial state of emergency was for 6 months, which

[3] General notice 240 of 2002; "2. In view of the rapid spread of HIV/AIDS among the population of Zimbabwe, the Minister hereby declares an emergency for a period of six months, with effect from the date of promulgation of this notice, for the purpose of enabling the State or a person authorised by the Minister under section 34 of the Act (a) to make or use any patented drug, including any antiretroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; (b) to

was extended for a further for five years up to 2008. On the 8th of April the Minister of Justice wrote a letter to Varichem Pharmaceuticals (Pvt) Ltd authorising them to produce ARV or other HIV/AIDS related drugs and to supply seventy five per cent of their production to the state (Osewe, Nkrumah, and Sackey 2008). The country's use of the compulsory route in 2003 is believed to have spurred local manufacture of ARVs thereby demonstrating political will and deployments of a policy infrastructure that promoted local pharmaceutical manufacturing (UNIDO 2011).

Four Zimbabwean pharmaceutical companies registered twenty generic ARVs with the Medicines Control Authority of Zimbabwe (MCAZ); Varichem (13), CAPS (4), Datlabs (1) and Plus 5 pharmaceuticals (2) (UNIDO, 2011b). However, only Varichem is currently manufacturing ARVs and it is the sole supplier of locally manufactured ARVs (UNIDO, 2007, 2011b). Varichem is also the only Zimbabwean local pharmaceutical company holding the WHO pre-qualification accreditation, and there has been growing concern at the multiple accreditations that African pharmaceutical companies need to meet and the concomitant cost of that regulation.

ARVs manufactured in Zimbabwe are predominantly first line treatment drugs falling under the broad classification of nucleoside reverse transcription inhibitors; Zidovudine (AZT, ZDV), Lamuvidine (3TC) and Stavudine (d4T), with Tenofovir (TDF) under

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import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions". Source: http://www.wipo.int/wipolex/en/text.jsp?file_id=214688 accessed 25 February 2014

development for both adult and paediatric formulations. For the non-nucleoside reverse transcription inhibitors, only Nevirapine (NVP) is manufactured in Zimbabwe, whilst Efavirenz (EFZ) is under formulation development. In the protease inhibitors class Indinavir (IDV) is the only ARV manufactured locally. As a consequence, local pharmaceutical manufacturers cannot compete for tenders that include ARVs currently not produced in the country, which is basically for all second line treatment drugs. The greater proportion of ARVs for the antiretroviral treatment (ART) programme in Zimbabwe, are imported from Indian companies such as Matrix, Ranbaxy, Cipla, Aurobindo and Hetero.

In 2008, local production capacity was 1.15 billion tablets and capsules, and local production benefitted from government procurement through special dispensations of supplying the public health sector without going to tender (Osewe et al, 2008). Government showed commitment by procuring the greater portion of ARV supplies from Varichem, and there was a price reduction as prior to local manufacture costs of drugs per month were US$ 30 and when local production came on stream Varivar sold at US$15 per month (Osewe et al, 2008).

4.3 Identified bottlenecks for pharmaceutical manufacture in Zimbabwe

In Zimbabwe's case, the existing studies identified key structural policy and practice hurdles hampering the growth of local pharmaceutical production, such as the need for technological capability improvement and innovation take off. Access to finance, finance capability (Banda, 2012), reduced drug procurement capacity by the public system, policy incoherence (health versus industry policy), and an unreliable supply of basic production inputs such as electricity and water, were named as key manufacturing bottlenecks..

Studies by UNIDO (2007; 2011), and Banda (2012) found out that lack of access to finance - especially long term finance ,as well as access to foreign currency to pay for key imports have been hampering local pharmaceutical production for over two decades. The shortage of foreign currency due to balance of payment deficits has had a negative impact on the provision of foreign currency denominated loans by local financial institutions. Coupled with a short-term focus to lending by local financial institutions, pharmaceutical companies have not had local financial support for capital investment financing (Banda 2013). As a result, Zimbabwean pharmaceutical companies have come to depend on internally generated funds to finance acquisition of plant, equipment and machinery, hampering innovation as well as the swift replacement of old machinery leading to inefficiencies and loss of competitiveness, while Indian pharmaceutical competitors have access to concessionary loans and export incentives.

Others reported that the main infrastructural hurdle faced by Zimbabwean local pharmaceutical companies are access to good potable water at high pressure to feed the reverse osmosis plants and intermittent supply of electricity (Banda, 2013), with companies resorting to sinking boreholes and installing standby generators to ensure consistent supply of water and electricity to the plant.

The economic instability experienced after the foreign-designed economic structural adjustment programme and high inflation have constrained government's financing ability for the public health system. This culminated in the collapse of the public health system between 2003 and 2009, and in high donor-dependence for financing public health systems and drug procurement (Managing Director Pharmaceutical Company B, 2011).

Policy incoherence has often been highlighted as an unhelpful factor for local pharmaceutical manufacture. Imports of finished ARV drugs into Zimbabwe are to date

duty-free, but excipients and other consumables with common use for the production of key drugs, are still subject to duty payment. When a compulsory licence was issued to Varichem, the government promised to purchase at least 75% of the ARVs produced locally; however when public funds became limited as inflation set-in, local procurement for the public health system declined, compromising the national manufacturing industry.

More recently, however, many observers have identified a policy shift towards supporting local manufacture of drugs. These days funds raised nationally can only be applied to buy locally-produced products – in the specific AIDS case, only for first line treatment ARVs. However as public pharmaceutical procurement is still critically dependent on external international grants, the government's discretionary power to buy locally is limited; the bulk of ARVs for donor-supported antiretroviral treatment are still imported through in-house institutional procurement vehicles, while ARVs for Global Fund-sponsored programmes are procured internationally by UNICEF, who is not inclined to source drugs in Zimbabwe.

The UNIDO reports also point out that generally pharmaceutical skills, human resources and lack of WHO certification are also key challenges for the industry. However, what Banda (2013) identified was that, while local skills for pharmaceutical production and quality assurance are still available in the country – including for technical positions in analytical chemistry and microbiology -, what seems to be lacking are experienced managers who could for spearhead national pharmaceutical research and development activities.

5 Determinants for the development of pharmaceutical production capacity in Mozambique and Zimbabwe

From the comparison of the two experiences, two models of development of local pharmaceutical capacity appeared to emerge; one based on established industrial institutions, actively supported by favorable state industrial policies in Zimbabwe, and the other supported by the international health community, supported by the government's business interest in developing a national pharmaceutical industry in Mozambique (Table 6).

Three aspects appeared to differ substantially in the two countries and critically influence the dynamics of local pharmaceutical production: (a) the economic situation; (b) the role of the international health donors, and; (c) the presence of an established local industry calling for favorable government regulation. On the one hand, Mozambique has experienced sustained growth in the last decade that spurred internal consumption and improved supply conditions. The economic outlook for the country is even more optimistic, as the recent discovery of natural resources hints at a future of double-digit growth for the next five years (World Bank 2013). On the other hand, Zimbabwe's economy has only recently come back to growth after a decade of falling GDP, which is believed to have had a long-term negative impact on local human capital, business environment and access to capital and to foreign currency (Banda 2013).

In the Mozambican case, the politics of South-South cooperation, drive and support from the international aid community were key determinants for establishing and grooming the only pharmaceutical factory in the country, both because of the role played by the Brazilian Technical Cooperation, and because of the vast international funds that have contributed to public purchase of pharmaceuticals since the 1980s (Barker 1983). Since the peace accord, Mozambique has been one of Africa's largest

recipients of health aid (Van de Maele, Evans, and Tan-Torres 2013), even to these days of natural resources-fuelled economic growth. The mining industry's interest have been claimed to be also behind Brazil's support to Mozambique's social sectors (Portal Vermelho 2010). Against such an economic backdrop, the Government of Mozambique is getting behind the national industrial development – perhaps driven by self-interest as many politicians happen to have personal involvement in State businesses – from directly participating in public production of pharmaceuticals, to agreeing to purchase the bulk of local output, to introducing duty exemptions for APIs and equalization preference to boast competitiveness of locally produced products.

<Insert table 6 here>

In Zimbabwe, the existence of a consolidated and diversified local pharmaceutical industry capable of producing nearly half the items in the national formulary, as well as the government's capacity to control quality of products in the market, were pointed out as factors affecting positively the industry's dynamics. In such a context the government also introduced favorable legislation for the local industry, such as compulsory licensing for the production of AIDS-related drugs in Zimbabwe, and the AIDS levy to finance the acquisition of drugs with locally-raised (and presumably more flexible funds). However, with the deterioration of the economic conditions, government's industrial policies have not been consistently supportive of the local industry, as a string of import duties and value added tax still contribute to turn locally-produced drugs uncompetitive vis-à-vis internationally produced ones.

To some extent, the AIDS epidemic and the introduction of Antiretroviral Treatment has come to change the pharmaceutical landscape in the two countries, as these have

(a) brought on a renewed interest in cheaper production of drugs; (b) attracted new international players and funds, and; (c) provided a new rationale and justification for government intervention in the pharmaceutical area.

Drugs have always been a crucial component of the health systems and health expenditures in the two countries. However, the global push for universal access to AIDS medicines has come to raise the interest around how drugs are produced, administered and priced. In Mozambique, although only 6 of SMM's product portfolio are ARVs, the factory is widely known as 'the ARVs factory'. Without the AIDS focus it seems reasonable to presume that no Brazilian-Mozambique pharmaceutical collaboration would have come into being, not least because of Brazil's specific expertise in the AIDS fight and the sense of urgency brought in by the epidemic in Southern Africa. In Zimbabwe the high HIV/AIDS prevalence rates of the nineties and the availability of relatively cheaper drugs from India, created the opportunity for some international donors to 'overrun' the economic sanctions and aid freeze, but also for the government to issue compulsory licenses to local producers to manufacture locally.

These renewed interests in AIDS drugs brought in fresh resources in both countries and a new player in Mozambique that would have not entered the pharmaceutical arena had it not been for the AIDS epidemic. Already one of the largest health sector donors in Mozambique, with the introduction of ART, the US became the single most important player in the AIDS area though US-based organizations such as the Clinton Health Access Initiative, the Presidential Emergency Plan for AIDS Relief, US Supply Chain Management System, Columbia Diseases Management, and a number of US-based NGOs dedicated to researching and supplying AIDS treatment. The proliferation of AIDS actors and the exponential rise of dedicated funds and project is for anyone to see in the country (Pfeiffer et al. 2010). In Zimbabwe AIDS funds and actors have

increased too, despite the international community's condemnation of the country's regime and the consequential limited influx of aid money.

The renewed interest in drugs and the extra resources brought in by the AIDS epidemic to a large extent created a window of opportunity for local producers in the two countries by increasing public demand for drugs, and by providing a rationale for government intervention to support local production of pharmaceuticals. Ballooning drug budgets, compulsory licenses, scrapping of import duties in both countries are evidence of the positive dividends accrued to the local pharmaceutical industries by the AIDS factor in the two countries. More recently, concerns on the availability of ARVs from Asian suppliers, have contributed to creating a sense that African countries should build up local manufacturing capacity in order to take full advantage of the opportunities offered by compulsory licensing for HIV/AIDS drugs (Owoeye 2014).

6 Discussion and conclusions

The analysis of the dynamics of the Mozambican and Zimbabwean pharmaceutical manufacturing sectors allows drawing few considerations for the wider debate on local production of drugs in Africa. Many of the shortcomings and bottlenecks to local production identified by the literature (Wilson, Kohler, and Ovtcharenko 2012) have been found in both countries, and are still considered to hamper the development of the sector: specialized human resources; uncertain and unfavorable business environment adding to local production costs; uncompetitive prices, and limited access to international markets. Our analysis has shown how such bottlenecks were overcome in the two case studies, either through training locally (Zimbabwe) or abroad (Mozambique), procuring goods and services from neighboring countries, or seeking access to wider regional markets.

As shown in our review of the literature on the subject, despite the persistence of the above stumbling blocks, pharmaceutical manufacturing initiatives appear to have multiplied across the African continent (see section 2). The experiences of Zimbabwe and Mozambique suggest two possible paths for this trend: one based on the pre-existence of the requisite developmental fundamentals such as Zimbabwe's strong industrial complex and training institutions, and one spurred by the international support to drug funding and to setting up Mozambique's factory. In both cases the role of favourable state industrial policies were crucial in issuing compulsory licensing for local factories and in finding extra local funds through the AIDS levy in Zimbabwe, and in participating directly in set up and management of a public factory in Mozambique.

It is beyond the scope of this paper to assess whether African pharmaceutical manufacturers can be competitive. Our observation of the factories in Mozambique and Zimbabwe suggest they may not be able to produce at competitive prices without some sort of subsidy or incentive structure, but that a different sort of benefit may be at the root of the recent proliferation of similar initiatives across the continent, from developing local industrial complex, to strengthening national production for national drug security. This is consistent with the findings from a recent study showing that albeit not necessarily cheaper, locally produced medicines in Tanzania are more likely to be found in rural settings, in comparison to their imported versions, possibly because of its reliance on more efficient private sector distribution networks (Mujinja et al. 2014). With the end of the TRIPS' transitional period low and middle-income countries can no longer rely on Chinese and Indian manufacturers for a steady supply of cheap drugs (Orsi et al. 2007). On the face of this, compulsory licensing and other TRIPS flexibilities have become key instruments to securitize drugs provision in LMIC (Nicol and Owoeye 2013). Although compulsory licensing has only been used sparingly by African countries (Beall and Kuhn 2012), and can be issued to a foreign third party, some

authors argue that only building local manufacturing capacity would allow African countries to take full advantage of the opportunities offered by TRIPS flexibilities (Owoeye 2014). Our analysis of the pharmaceutical manufacturing dynamics in Mozambique and Zimbabwe suggests that the combination of Africa's economic development, improving industrial conditions, guarantees of support from national governments pressing for national drug security, and increased drug funds from the international community partly driven by the AIDS epidemic, may be tipping the balance and convince manufacturers to enter the business of local pharmaceutical production in Africa, despite the persistence of doubts on its short-term profitability and viability.

There is a temptation to extract conclusions from our study on the opportunity for African national governments to protect their nascent pharmaceutical manufacturing sector. Although some authors have highlighted the positives in the Brazilian domestic experience of having a state-owned pharmaceutical industry (Flynn 2008), our study fails to provide direct evidence to support the argument that protectionist measures in Africa may foster a healthy and competitive local industry, contributing to increase population access to drugs. Having a presence in the pharmaceutical market clearly appears to give an advantage to the Mozambican and Zimbabwean governments in terms of accessing information on production costs and of adapting chemical formulations to local epidemiological needs. Nonetheless, whether cash-strapped African governments should invest in creating local pharmaceutical manufacturing capacity, is still something that needs to be weighed against the competing priorities.

Some scholars have highlighted how the unresolved tension between public health and industrial policy objectives pervades the discourse on local production of drugs, meddling the arguments on the subject and polarizing the camp of supporters and detractors (Kaplan and Laing 2005; WHO 2011). Some of these tensions were visible

in our two case-studies, where advocates of the public health arguments – lining up the international health community, local medical organisations, patient protection institutions and Ministries of Health – refused to consider the demands from the local industry for favourable industrial policies, and the local business community – lining up private sector representatives, national business organizations and most national governments' departments – failed to see the importance of extracting the most of scant national drug budgets to expand the population's access to drugs. Some of the most recent WHO/UNIDO's work on the subject goes some way in the direction of identifying common grounds for a discussion between the two factions, that should aim at guaranteeing minimum outcomes such as: quality standards of locally produced drugs, health security of drug supply, selection of essential drugs, affordable prices, and innovation for more suitable formulations to local conditions (WHO 2011). But a more sustained effort is needed to create a comprehensive framework to incorporate the public health and industrial policy views, laying out basic ground rules and identifying potential common interests.

Finally, our study shows that AIDS treatment and ARV production has come to open new opportunities to local pharmaceutical production, because of the mobilization of extra resources for drugs procurement – particularly in the case of Mozambique - the interests it has raised on ARV treatment, and the justification it provided for local governments to resort to TRIPS flexibilities for public health purposes, as in the case of Zimbabwe's compulsory licensing experience. Amid concerns that the availability of cheap drugs from Asian producers may soon become more circumscribed (Owoeye 2014), both the Mozambican and Zimbabwean cases demonstrate that such opportunities need to be managed by national governments, as the ARV funds made available by the international community may not be completely secure in the long-run, nor sufficiently flexible to be re-directed from internationally procured drugs to locally-

produced ones, as the current financing of ARVs public procurement in Mozambique eloquently shows. Under these circumstances, investing in the local pharmaceutical industry suddenly appears as a sensible option for national governments, while diversifying away from the lucrative but volatile ARV business may become a necessity for local producers.

Tables and figures

Table 1: Mozambique and Zimbabwe's basic health and healthcare indicators

Indicator	Mozambique	Zimbabwe
Population	25,203,395	13,724,317
Maternal mortality ratio (per 100,000 live births)	490	570
Life expectancy at birth	49	56
<5 mortality (per 1,000 live births)	90	90
HIV prevalence (15-49)	11.3	14.9
People living with HIV/AIDS	1,600,000	1,400,000
Proportion of ART coverage among advanced infections	44	77
GDP per capita	579	788
Health expenditures per capita	35	87
Total HIV/AIDS spending (USD millions)**	144.9	100.5
Number of pharmacists registered in the country*	447	678
Pharmaceutical personnel density (per 1000 habitants)*	0.04	0.19

*Currency: 2012 USD unless differently stated. Source: The World Bank Database; * Global Health Observatory Repository (2008 and 2009 data); ** UNAIDS 2012*

Table 2: Public sector drug imports value, by source and type of health programme (2012 USD)

Health programme and associated drugs	MoH-managed funds*	External funds (in kind donations)	Total
Hospital drugs	11,861,471	1,200,883	13,062,354
Primary care drug kits	8,708,824	0	8,708,824
Community health	3,870,588	7,217,900	11,088,488
STD and HIV-SIDA	0	48,750,977	48,750,977
TB	0	249,550	249,550
Malaria	0	24,124,599	24,124,599
Blood banks	967,647	0	967,647
Oral health	290,294	0	290,294
Surgical supplies	10,111,912	0	10,111,912
Laboratory supplies	2,497,000	0	2,497,000
Imagiology	1,741,765	0	1,741,765
Total	40,049,500	81,543,908	121,593,408

*Source: CMAM, 2012. *includes both State Budget and PROSAUDE funds*

Table 3: Public sector drug expenditures, by source of funding (2012 USD)

Source of funding	HIV/AIDS drugs	All other drugs	Total
State Budget	0	22,027,225	22,027,225
PROSAUDE funds	0	18,022,275	18,022,275
Global Fund	1,742,252	2,315,328	4,057,579
GDF	0	249,550	249,550
World Bank	13,846,255	11,260,563	25,106,818
USAID	27,479,319	11,461,346	38,940,665
UN (UNFPA and UNICEF)	0	7,506,145	7,506,145
CHAI	5,683,151	0	5,683,151
Total	48,750,977	32,792,932	121,593,408

Source: CMAM, 2012

Table 4: Zimbabwe's imports, exports and trade balance for pharmaceuticals between 2006-2011

(US$ million at current prices)

	2006	2007	2008	2009	2010	2011
Imports	39.2	73.5	77.2	81.1	85.1	89.4
Exports	1.63	1.15	1.12	1.08	1.05	1.02
Trade Balance	-37.5	-72.4	-76.1	-80.0	-84.1	-88.4

Source : Musundire (2012) who compiled the data from UN Comtrade Database DESA/UNSD

Table 5: Application of AIDS levy funds across spending categories (2009-2012)

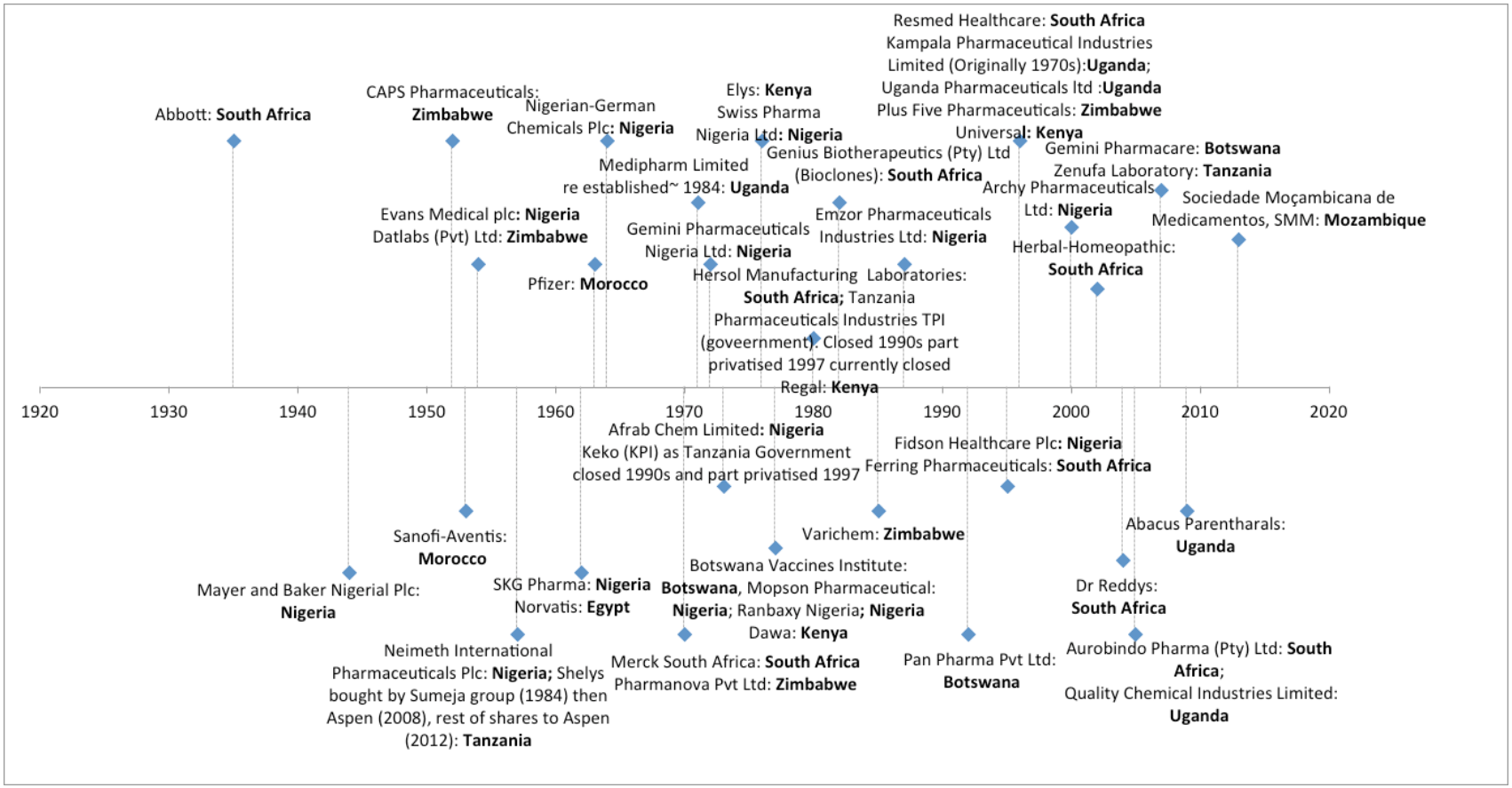
Application of funds: US$ million	2009	2010	2011	2012
ARVs	0.89	3.31	10.14	18.60
Reagents	0	0.44	2.50	1.72
Kits	0.36	0.59	0.90	0.002
Equipment	0	2.32	1.97	1.49
Outreach and Support	0	0.002	1.15	1.01

Table 6: Key factors for the development of the pharmaceutical industry Mozambique and Zimbabwe

Type of factor	Mozambique	Zimbabwe
Policy and institutional	Direct involvement international agencies in production (Brazilian technical cooperation); The politics of South-south cooperation in generating business opportunities through cooperation programmes between Brazil and Mozambique;	Existence of a consolidated local private pharmaceutical industry (9 producers) capable of manufacturing 47% of items in EDL;
	Government direct management of production and procurement;	Low historical dependence on imported drugs and capacity to sell to the wide region;
	Favourable government regulation for local production (equalization preference, no import duties for API);	Favourable government policy and regulations (AIDS levy, TRIPS flexibility, commitment to buy 75% of local output);
		Strong tertiary education sector with emphasis on technical training through; Strong link between universities, polytechnics and industry (Zimdef);
Economic	Sustained economic growth driven by the discovery of natural resources;	Zimbabwe's Industrial development trajectory and exclusion from the world. Federation market initial impetus for local production based on import

		substitution agenda during sanctions and UDI;
	Presence of common fund for drugs managed by MoH;	Government direct funding for the drug bill through the AIDS levy as well as budgetary allocations;
	Competitive prices thanks to subsidies;	New companies formed by executives from existing companies; Technological spill-overs;
	Weak private sector demand, accounting for less than 15% of the market;	Weak public health demand for drugs due to the country's economic downturn. The private health sector in comparison to the public health sector is small in Zimbabwe.
	Sustained public sector demand supported by international funds.	

Figure 1: Evolution of major pharmaceutical manufacturing companies in the African continent for selected countries



Source: UNIDO, GIZ and pharmaceutical companies' individual websites

Annex I – List of pharmaceutical products to be produced by SMM in Mozambique

Type of product	Product name and formulation
Drippings	
1	Lactate Ringer + AD set 1000 ml injectable
2	Glucose 1000ml (5%) inj.
3	Glucose 500 ml (5%) inj.)
4	Chlorate of Sodium 1000ml (0.9%) inj.
5	Chlorate of Sodium 500ml (0.9%) inj.
Antiretroviral products	
6	Lamivudine 150mg cps.
7	Ribavirin 250mg cps.
8	Nevirapina 200mg comprimidos
9	Lamivudine + Zidovudine + Nevirapine (150+300+200) mg cps
10	Lamivudine + Zidovudine (150+300) mg cps.
11	Zidovudine 100mg cps.
Other solid pharmaceutical compounds	
12	Folic Acid 5mg cps.
13	Metronidazole 250mg cps
14	Prednisone 5mg cps

15	Prednisone 20mg cps
16	Glibenclamide 5mg cps
17	Hydrochlorothiazide 25mg cps

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